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The importance of developing and managing a well-defined regulatory strategy

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Abstract

A comprehensive regulatory strategy exemplifies expectations, and clarity for the entire project plan from early development to commercialization. In addition, it enables the identification of potential impediments, and creates a systematic guide for the progression of the project. Early regulatory guidance is an invaluable tool for long-term project projections, and to meet defined deliverables, and goals.

Regulatory strategy incorporates the development plan, outstanding issues, background information, applicable regulatory guidance's, and recommendations for implementation. Ultimately, a regulatory strategic plan is a reflection of the corporate culture, and commitment to manufacture safe and efficacious, quality products. Following a well-designed strategic plan could result in significant savings with revenue and time, and minimizes risk for the manufacturer.

Biography

Chitra Edwin is a consultant, and principal for Biotechnology Consulting Solutions, Ltd. She has significant product development and management experience in biotechnology, device and IVD companies. She has been a key member in the development of products for infectious diseases, and oncology that have regulatory approval. She is an Adjunct Associate Professor of Pharmaceutical Sciences, University of Cincinnati. Dr. Edwin obtained her Ph.D. from the University of Minnesota, and post-doctoral training at the Harvard Medical School, and the Dana Farber Cancer Institute. She has RAPS certification. She is a Board member of Opus Institutional Review Board (IRB).